SCIENTIFIC OPINION

Scientific Opinion on the safety evaluation of the process 'Evertis Iberica', based on EREMA MPR technology, used to recycle post-consumer PET into food contact materials[1]

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)[2,3]

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ABSTRACT

This scientific opinion of the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) deals with the safety assessment of the recycling process Evertis Iberica (EU register number RECYC0123), which is based on the EREMA Multi-Purpose Reactor (MPR) technology. The input to this process is washed and dried polyethylene terephthalate (PET) flakes originating from collected post-consumer PET containers and containing no more than 5 % PET from non-food consumer applications. In this technology, post-consumer washed and dried PET flakes are heated in a continuous reactor under vacuum. Having examined the results of the challenge test provided, the Panel concluded that the continuous reactor step (step 2) is the critical step that determines the decontamination efficiency. The operating parameters which control the performance of this step are well defined and are temperature, pressure and residence time. It was demonstrated that the recycling process under evaluation is able to ensure that the level of migration of potential unknown contaminants into food is below a conservatively modelled migration of 0.15 µg/kg food, derived from an exposure scenario for toddlers. The Panel concluded that the recycled PET obtained from the process Evertis Iberica is not considered of safety concern when used for the manufacture of thermoformed trays and containers made with up to 100 % recycled post-consumer PET, and used for contact with all types of foodstuffs, except packaged water, for long-term storage at room temperature, with or without hotfill. Thermoforming trays are not intended to be used, and should not be used, in microwave and conventional ovens.

KEY WORDS

EREMA MPR, food contact material, plastic, polyethylene terephthalate (PET), recycling process, safety assessment

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[1] On request from the Ministério da Agricultura e do Mar, Portugal, Question No EFSA-Q-2014-00884, adopted on 6 May 2015.

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SUMMARY

In accordance with Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials intended to come into contact with foods, EFSA is requested to evaluate processes for recycling plastic waste. In this context, the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) evaluated the process ‘Evertis Iberica’.

The Ministério da Agricultura e do Mar, Portugal, requested the evaluation of the recycling process ‘Evertis Iberica’, submitted on behalf of the company Evertis Ibérica S.A., Portugal. The recycling process has been allocated the European Union register number RECYC0123. It is deemed to recycle polyethylene terephthalate (PET) flakes from PET containers collected through post-consumer collection systems. According to the applicant, the recycled PET obtained from this process is intended to be used up to 90 % in mixtures with virgin PET in the manufacture of thermoformed trays and containers intended for contact with all types of foodstuffs, except packaged water, for long-term storage at room temperature, with or without hotfill.

The process comprises two steps. First, the collected post-consumer PET containers are processed into washed and dried flakes (step 1). Second, the dried flakes are used as the input for the EREMA Multi-Purpose Reactor (MPR) decontamination technology (step 2).

Detailed specifications for the input material are provided for the submitted recycling process and the proportion of non-food containers is reported to be below 5 %.

A challenge test was conducted with surrogate contaminants in an industrial-scale plant in step 2 (continuous reactor) of the process to measure its decontamination efficiency. Since a mixture of flakes not contaminated with surrogates (white) and flakes spiked with surrogates (green) was used for this challenge test, the Panel calculated the decontamination efficiency by taking into account also the amount of contaminants possibly transferred to the white flakes as a result of cross-contamination during the challenge test.

Step 2 was considered by the Panel to be the critical step for the removal of possible contaminants and should be kept under control to guarantee the decontamination performance of the process.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, ranging from 93.2 % to 98.8 %, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C*res*), in accordance with the evaluation procedure described in ‘Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food’ (EFSA CEF Panel, 2011). According to these evaluation principles, the C*res* should not be higher than a modelled concentration of contaminants in PET (C*mod*) corresponding to a migration, after one year at 25 °C, which cannot give rise to a dietary exposure exceeding 0.0025 µg/kg body weight (bw)/day, the exposure threshold below which the risk to human health would be negligible. Since the process produces PET intended to be used in the manufacture of trays and containers not used to package water (since water could be used to prepare infant formula), the exposure scenario for toddlers has been applied as a worst case, where a maximum dietary exposure of 0.0025 µg/kg bw/day corresponds to a maximum migration of 0.15 µg/kg of the contaminant into a toddler’s food. Therefore, the corresponding migration value of 0.15 µg/kg (scenario for toddlers) into food has been used to calculate the C*mod*. According to these criteria, the recycling process under evaluation using EREMA MPR technology is able to ensure that the level of unknown contaminants in recycled PET is below a calculated concentration (C*mod*) when the recycled flakes are used at up to 100 %.

The Panel considered that the process is well characterised and that the main steps used to recycle PET flakes into decontaminated PET flakes have been identified. Having examined the results of the challenge test provided, the Panel concluded that decontamination in a continuous reactor at high temperature and under vacuum (step 2) is the critical step for the decontamination efficiency. The

operating parameters which control the performance of this step are temperature, pressure and residence time. Therefore, the Panel considered that the recycling process Evertis Iberica is able to reduce any foreseeable accidental contamination of post-consumer food contact PET to a concentration that does not give rise to concern of a risk to human health if:

- it is operated under conditions that are at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process;
- the input for process is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with EU legislation on food contact materials and contain no more than 5 % PET from non-food consumer applications.

The Panel concluded that the recycled PET obtained from the process Evertis Iberica intended for the manufacture of thermoformed trays and containers for contact with all types of foodstuff, except packaged water, for long-term storage at room temperature, with or without hotfill, is not considered of safety concern, when made with up to 100 % recycled post-consumer PET. Thermoforming trays are not intended to be used, and should not be used, in microwave and conventional ovens.

The Panel recommended that it should be verified periodically, as part of Good Manufacturing Practice, that, as foreseen in Regulation (EC) No 282/2008, Article 4b, the input must originate from plastic materials and articles that have been manufactured in accordance with EU legislation on food contact materials and articles, and that the proportion of PET from non-food consumer applications in the input to be recycled is no more than 5 %. Critical steps should be monitored and kept under control; supporting documentation describing how it will be ensured that the critical steps are operated under conditions at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process should be available.

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BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE LEGISLATION

Recycled plastic materials and articles shall only be placed on the market for food contact if they contain recycled plastic obtained from an authorised recycling process. Before a recycling process is authorized, EFSA´s opinion on its safety is required. This procedure has been established in Article 5 of the Regulation (EC) No 282/2008[4] of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods and Articles 8 and 9 of the Regulation (EC) No 1935/2004[5] of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

According to this procedure, the industry submits applications to the Member States competent Authorities which transmit the applications to EFSA for evaluation. Each application is supported by a technical dossier submitted by the industry following the EFSA guidelines for the submission of an application for safety evaluation by EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorization (EFSA, 2008).

In this case, EFSA received from the Ministério da Agricultura e do Mar, Portugal, an application for evaluation of PET recycling process Evertis Iberica, EU register number RECYC0123.

EFSA is required by Article 5 of Regulation (EC) No 282/2008 of the Commission of 27 March 2008 on recycled plastic materials intended to come into contact with foods to carry out risk assessments on the risks originating from the migration of substances from recycled food contact plastic materials and articles into food and deliver a scientific opinion on the recycling process examined.

According to Article 4 of Regulation (EC) No 282/2008, EFSA will evaluate whether it has been demonstrated in a challenge test, or by other appropriate scientific evidence that the recycling process Evertis Iberica is able to reduce any contamination of the plastic input to a concentration that does not pose a risk to human health. The PET materials and articles used as input of the process as well as the conditions of use of the recycled PET make part of this evaluation.

[4] Regulation (EC) No 282/2008 of the European parliament and of the council of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006. OJ L 86, 28.03.2008, p. 9–18.

[5] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. OJ L 338, 13.11.2004, p. 4–17.

ASSESSMENT

1. Introduction

The European Food Safety Authority (EFSA) was asked by the Ministério da Agricultura e do Mar, Portugal, to evaluate the safety of the recycling process Evertis Iberica with the European Union (EU) register number RECYC0123. The request was registered in EFSA's register of received questions under the number EFSA-Q-2014-00884. The dossier was submitted on behalf of Evertis Ibérica, S.A.

The dossiers submitted for evaluation followed the EFSA guidelines for the submission of an application for safety evaluation by EFSA of a recycling process to produce recycled plastics intended to be used for the manufacture of materials and articles in contact with food, prior to its authorisation (EFSA, 2008).

2. General information

According to the applicant, the recycling process Evertis Iberica is intended to recycle post-consumer polyethylene terephthalate (PET) articles to produce recycled PET flakes using EREMA Multi-Purpose Reactor (MPR) technology. According to the applicant, the recycled flakes are intended to be used up to 90 % in mixtures with virgin PET, in the manufacture of thermoformed trays and containers, intended for contact with all types of foodstuffs, except packaged water. These final materials and articles are intended to be used for long-term storage at room temperature, with or without hotfill.

3. Description of the process

3.1. General description

The recycling process Evertis Iberica produces recycled PET flakes from containers, mainly bottles, coming from post-consumer collection systems (kerbside and deposit collection systems). The recycling process comprises two steps, as described below.

Step 1: input

- In step 1, post-consumer PET containers are ground and processed into hot caustic washed and dried flakes, which are used as input to the next step. The washed flakes are produced in house or by a third party.

Step 2: decontamination and production of recycled PET material

- In step 2, the flakes are decontaminated and (partly) crystallised at high temperature and under vacuum in a decontamination reactor (MPR).

Recycled PET flakes, the final products of the process, are checked against technical requirements on intrinsic viscosity, colour and black spots. According to the applicant, recycled flakes are intended to be converted by other companies into sheets, containing up to 90 % recycled flakes in mixtures with virgin PET, for thermoforming of trays and containers for food contact applications, such as for fruit, vegetables, cooked and uncooked meats, dairy products and desserts. Thermoforming trays are not intended to be used in microwave and conventional ovens.

The operating conditions of the process have been provided to EFSA.

3.2. Characterisation of the input

According to the applicant, the input for the recycling process Evertis Iberica is hot caustic washed and dried flakes obtained from PET containers previously used for food packaging, obtained from post-consumer collection systems (kerbside and deposit collection systems). However, a small fraction may originate from non-food applications such as soap bottles, mouthwash bottles, kitchen cleaning product bottles, etc. According to the applicant, the fraction of non-food containers depends on the re-collection system. On the basis of market share data, the applicant estimated this fraction to be below 5 %.

Technical data for the hot caustic washed and dried flakes are provided for the submitted recycling process, such as information on the residual content of poly(vinyl chloride) (PVC), glue, polyolefins, cellulose, metals, polyamides and physical properties (see Appendix A).

4. EREMA MPR technology

4.1. Description of the main steps

The recycling process Evertis Iberica uses EREMA MPR technology, which is described below and for which the general scheme provided by the applicant is reported in Figure 1. Hot caustic washed and dried flakes from step 1 are used as the input for the subsequent step, which is:

- decontamination in a continuous reactor (step 2):
  - In this step, the flakes are introduced into a continuous MPR equipped with a bottom-mounted rotating mixing device, in which vacuum and temperature are applied for a predefined residence time. During this decontamination step, the flakes are (partly) crystallised. These process conditions favour the vaporisation of possible contaminants and crystallisation of PET flakes.

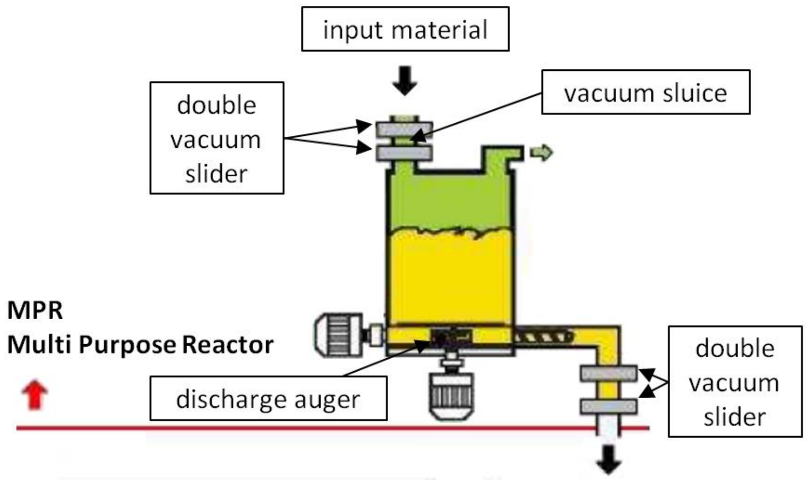


Figure 1: General scheme of EREMA MPR technology

The process is operated under defined operating parameters of temperature, pressure and residence time.

4.2. Decontamination efficiency of the recycling process

To demonstrate the decontamination efficiency of the recycling process Evertis Iberica, a challenge test on EREMA MPR technology was submitted to EFSA.

PET flakes were contaminated with selected chemicals, toluene, chlorobenzene, chloroform, methyl salicylate, phenylcyclohexane, benzophenone and methyl stearate, which were used as surrogate contaminants. The surrogates were chosen in agreement with EFSA guidelines and in accordance with the recommendations of the US Food and Drug Administration. The surrogates include chemicals with different molecular weights and polarities to cover possible chemical classes of contaminants of concern and were demonstrated to be suitable to monitor the behaviour of PET during recycling (EFSA, 2008).

For the preparation of the contaminated PET flakes, 5 kg of conventionally recycled[6] post-consumer PET flakes of green colour was soaked in a mixture of the surrogates, then this masterbatch was mixed with 50 kg of PET flakes, and stored for seven days at 50 °C. The contaminated flakes were washed and rinsed in a batch process in a pilot-scale plant. The concentration of surrogates in this material was determined.

The EREMA MPR technology was challenged using an industrial-scale plant. To process a sufficiently large amount of material, compatible with the high capacity of the continuous industrial plant, the reactor was initially fed with non-contaminated flakes (white) and, after process conditions were stabilised, with a defined amount of contaminated flakes (green) and then with a much larger quantity of non-contaminated flakes (white). The flakes were continuously fed into the reactor. Samples were taken at the outlet of the reactor at regular intervals. The green flakes were separated from the white flakes and the evolution of the fraction of green flakes over time (residence time distribution curve) was determined by weighing. The green flakes were then analysed for the residual concentrations of the applied surrogates.

The Panel noted that decontamination efficiencies, calculated only on the basis of residual surrogates in the contaminated (green) flakes, could be overestimated. In fact, cross-contamination by transfer of contaminants from green to white flakes may occur.[7]

Therefore, to take into account the cross-contamination phenomenon, and in the absence of specific data provided by the applicant, some assumptions and considerations were made, as follows:

- The mass fraction of green to white flakes at each sampling time, was derived from the data provided. A best-fit residence time distribution curve was derived from the experimental figures and was used to calculate the percentage of green and white flakes at different residence times.
- The residual concentrations of surrogates in the green flakes after decontamination were derived from the data provided. A best-fit curve was derived from the experimental figures and was used to interpolate the residual concentrations in green flakes at different residence times.
- The Panel made the assumption that cross-contamination of surrogates from green to white flakes in the reactor occurred to the extent of 10 % of the residual concentration measured in the green flakes. This percentage reflects experience gained from previous evaluations.

To take into account the cross-contamination between green and white flakes, the evolution of the total residual surrogate content at the outlet of the continuous reactor (step 2) as a function of (residence) time was calculated by adding the residual surrogate amount in green flakes to the residual surrogate amount in white flakes. The residual surrogate amount in green flakes was calculated from the mass fraction of green flakes multiplied by the residual concentration of surrogates in the green flakes. The residual surrogate amount in white flakes was calculated from the mass fraction of white flakes multiplied by the residual concentration of surrogates in the white flakes (assumption of 10 % of the concentration measured in the green flakes). The calculated total residual surrogate amounts were compared with the initial contamination level of green flakes at the inlet of the reactor to derive the decontamination efficiencies (see Table 1).

[6] Conventional recycling includes commonly sorting, grinding, washing and drying steps and produces washed and dried flakes.

[7] 'Cross-contamination', as defined in 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food', is the transfer of surrogates from the initially contaminated to the initially non-contaminated flakes (EFSA CEF Panel, 2011).

Table 1: Efficiencies of the decontamination of the continuous reactor (step 2)

Surrogates	Concentration [a] of surrogates before step 2 (mg/kg PET)	Concentration [b] of surrogates after step 2 (mg/kg PET)	Decontamination efficiency [c] (%)
Toluene	202	0.31	98.6
Chlorobenzene	361	0.59	98.5
Chloroform	291	0.38	98.8
Methyl salicylate	143	1.79	95.0
Phenylcyclohexane	364	1.93	95.2
Benzophenone	480	3.58	93.2
Methyl stearate	360	1.57	96.0

(a): Initial concentration in the contaminated PET flakes.
(b): Residual concentration calculated for green flakes after decontamination.
(c): Decontamination efficiency of the step 2 reactor in the challenge test and after correction for cross-contamination (see text).

The decontamination efficiencies, as presented in Table 1, were calculated at the time of exit from the continuous reactor (step 2) in the challenge test. The decontamination efficiencies ranged from 93.2 % for benzophenone up to 98.8 % for chloroform.

5. Discussion

Considering the high temperatures used during the process, the possibility of contamination by microorganisms can be discounted. Therefore, this evaluation focuses on the chemical safety of the final product.

Technical data, such as information on the residual content of PVC, glue, polyolefins, cellulose, metals and polyamides, and physical properties, are provided for the input materials, hot caustic washed flakes (step 1), for the submitted recycling process. The input materials are produced from PET containers previously used for food packaging collected through post-consumer collection systems. However, a small fraction of the input may originate from non-food applications such as soap bottles, mouthwash bottles, kitchen cleaning product bottles, etc. According to the applicant, the fraction of non-food containers depends on the collection system and, on the basis of market share data, it is below 5 %, as recommended by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) in its 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF Panel, 2011).

The process is well described. The production of washed and dried flakes from collected containers (step 1) is carried out in-house or by a third party. According to the applicant, this step is under control. In the next step of EREMA MPR technology, the PET flakes are decontaminated a MPR decontamination reactor (step 2). The operating parameters of temperature, pressure and residence time for step 2 have been provided to EFSA.

A challenge test on step 2 (continuous decontamination reactor) of the process was carried out in an industrial-scale plant to measure the decontamination efficiency. In this challenge test, the continuous decontamination reactor was operated under pressure and temperature conditions equivalent to those used for the commercial process. The challenge test was performed in accordance with EFSA guidelines (EFSA, 2008). Since a mixture of non-contaminated flakes (white) and flakes spiked with surrogates (green) was collected at the outlet of the reactor used for this challenge test, the Panel calculated the decontamination efficiency taking into account the amount of surrogates possibly transferred to the white flakes as a result of cross-contamination during the challenge test. The Panel considered that decontamination in a continuous reactor (step 2) is the critical step for the decontamination efficiency of the process. Consequently, the temperature, pressure and residence time parameters of step 2 should be controlled to guarantee the performance of decontamination. These parameters have been provided to EFSA.

The decontamination efficiencies obtained for each surrogate contaminant from the challenge test, at the different residence times, ranging from 93.2 % to 98.8%, have been used to calculate the residual concentrations of potential unknown contaminants in PET (C*res*) in accordance with the evaluation procedure described in 'Scientific opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food' (EFSA CEF, 2011; Appendix B). By applying the decontamination efficiency percentages to the reference contamination level of 3 mg/kg PET, the C*res* values for the different surrogates are obtained (see Table 2).

According to the evaluation principles (EFSA CEF Panel, 2011), the C*res* value should not be higher than a modelled concentration in PET (C*mod*) corresponding to a migration, after one year at 25 °C, which cannot give rise to a dietary exposure exceeding 0.0025 μg/kg bw/day, the exposure threshold below which the risk to human health would be negligible.[8] Because the recycled PET is intended to be used in the manufacture of trays and containers not used to package water (since water could be used to prepare infant formula), the exposure scenario for toddlers has been applied as worst case, where a maximum dietary exposure of 0.0025 μg/kg bw/day corresponds to a maximum migration of 0.15 μg/kg of the contaminant into a toddler's food. Therefore, the corresponding migration of 0.15 μg/kg (scenario for toddlers) into food has been used to calculate C*mod* (EFSA CEF Panel, 2011). If the PET produced by a recycling process is used up to 100 % to produce new articles and they do not meet these targets, recycled PET should be mixed with virgin PET to make sure that the C*res* value does not exceed the C*mod* value. The Panel established the maximum percentages of recycled PET in final articles for which the risk to human health is demonstrated to be negligible. These percentages are reported in Table 2 for the scenario of toddlers. The percentages of recycled PET reported in Table 2 are, therefore, the maximum percentages for which the risk to human health is demonstrated to be negligible and may differ from the initial request from the applicant. The relationship between the key parameters for the evaluation scheme is reported in Appendix B.

Table 2: Decontamination efficiency from challenge test, residual concentration of surrogate contaminants in recycled PET (C*res*) and calculated concentration of surrogate contaminants in PET (C*mod*) corresponding to a modelled migration of 0.15 μg/kg food after one year at 25 °C

Surrogates	Decontamination efficiency (%)	C*res* for 100 % rPET (mg/kg PET)	C*mod* (mg/kg PET)
Toluene	98.6	0.04	0.13
Chlorobenzene	98.5	0.04	0.15
Chloroform	98.8	0.04	0.15
Methyl salicylate	95.0	0.15	0.20
Phenylcyclohexane	95.2	0.14	0.21
Benzophenone	93.2	0.20	0.24
Methyl stearate	96.0	0.12	0.47

On the basis of the data provided from the challenge test and the applied conservative assumptions, the Panel considered that the recycling process under evaluation using EREMA MPR technology is able to ensure that the level of migration of unknown contaminants from the recycled PET into food is below the conservatively modelled migration of 0.15 μg/kg food (derived from a exposure scenario for toddlers) when the recycled PET is used up to 100 % in mixtures with virgin PET, at which level the risk to human health would be negligible.

[8] 0.0025 μg/kg bw/day is the human exposure threshold value for chemicals with structural alerts raising concern for potential genotoxicity, below which the risk to human health would be negligible (EFSA CEF Panel, 2011).

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The Panel considered that process is well characterised and the main steps used to recycle PET flakes into decontaminated PET flakes have been identified. Having examined the challenge test provided, the Panel concluded that the decontamination in a continuous reactor (step 2) is the critical step for the decontamination efficiency of the process. The operating parameters to control its performance are temperature, pressure and residence time. Therefore, the Panel considered that the recycling process Evertis Iberica is able to reduce any foreseeable accidental contamination of post-consumer food contact PET to a concentration that does not give rise to concern of a risk to human health if:

- they are operated under conditions that are at least as severe as those obtained from the challenge test used to measure the decontamination efficiency of the process;
- the input is washed and dried post-consumer PET flakes originating from materials and articles that have been manufactured in accordance with EU legislation on food contact materials containing no more than 5 % of PET from non-food consumer applications.

The Panel concluded that the recycled PET obtained from the process Evertis Iberica intended for the manufacture of thermoformed trays and containers for contact with all types of foodstuff, except packaged water, for long-term storage at room temperature, with or without hotfill, is not considered of safety concern, when made with up to 100 % recycled post-consumer PET. Thermoforming trays are not intended to be used in microwave and conventional ovens.

RECOMMENDATIONS

The Panel recommended that it should be verified periodically, as part of Good Manufacturing Practice, that, as foreseen in Regulation (EC) No 282/2008, Article 4b, the input must originate from plastic materials and articles that have been manufactured in accordance with the Community legislation on food contact materials and articles, and that the proportion of PET from non-food consumer applications in the input to be recycled is no more than 5 %. Critical steps should be monitored and kept under control; supporting documentation describing how it will be ensured that the critical steps are operated under conditions at least as severe as those applied in the challenge test used to measure the decontamination efficiency of the process should be available.

DOCUMENTATION PROVIDED TO EFSA

1. Dossier ‘Evertis Iberica’. December 2014. Submitted on behalf of Evertis Iberica S.A.

2. Additional data for Dossier ‘Evertis Iberica’. March 2015. Submitted on behalf of Evertis Iberica S.A.

REFERENCES

EFSA (European Food Safety Authority), 2008. Guidelines for the submission of an application for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food, prior to its authorisation. The EFSA Journal 2008, 717, 2–12.

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF), 2011. Scientific Opinion on the criteria to be used for safety evaluation of a mechanical recycling process to produce recycled PET intended to be used for manufacture of materials and articles in contact with food. EFSA Journal 2011;9(7):2184, 25 pp. doi:10.2903/j.efsa.2011.2184

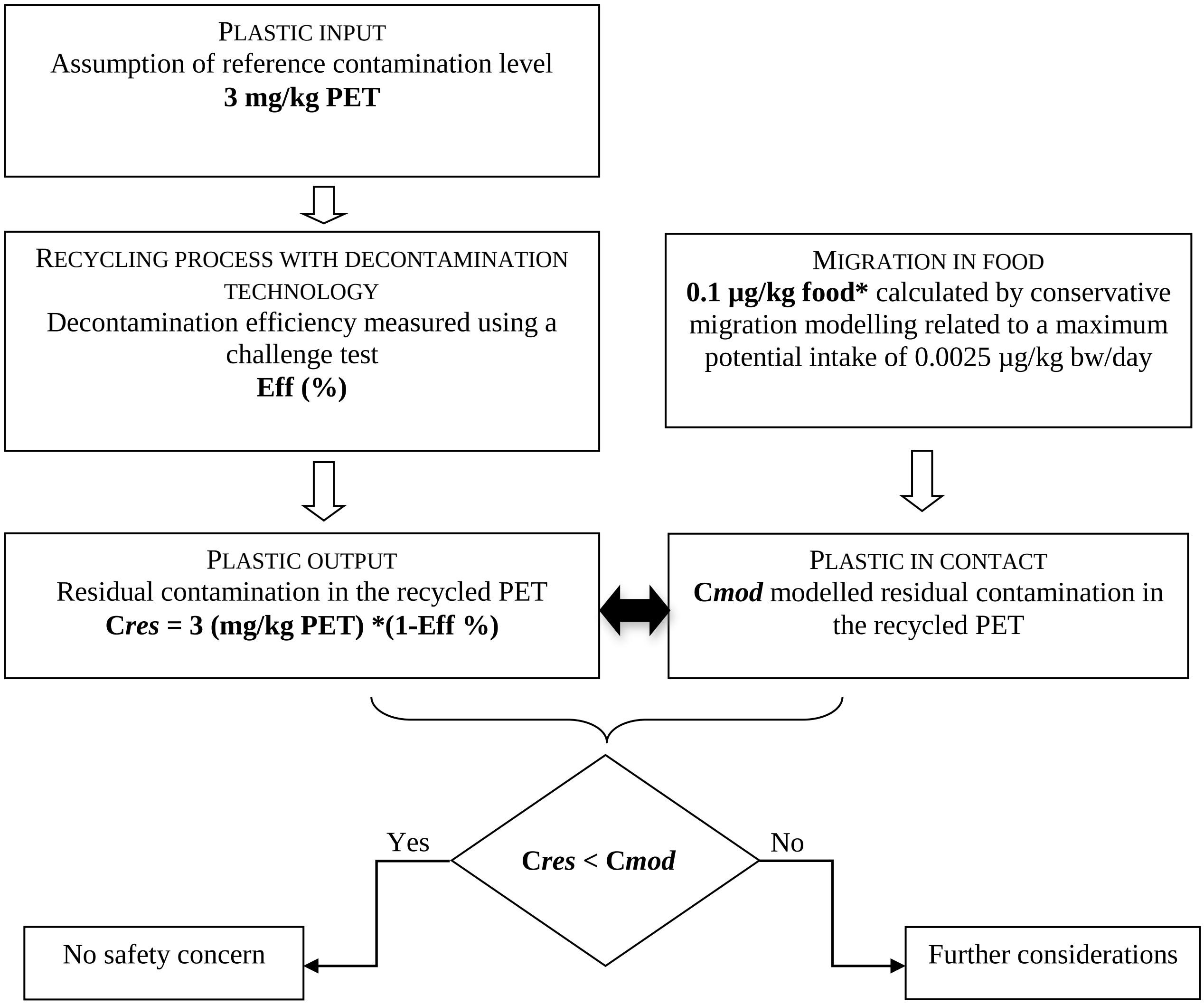
APPENDICES

Appendix A. Technical data of the washed flakes as provided by the applicant

Washed and dried flakes used for the Evertis Iberica recycling process.

Parameter	**Value**
Moisture max.	1.0 %
Moisture variation	± 0.3 % h^{-1}
Bulk density	230 – 850 kg m^{-3}
Bulk density variation	± 150 kg m^{-3} h^{-1}
Material temperature	10 – 60 °C
Material temperature variation	± 10 °C h^{-1}
PVC max.	200 ppm
Glue max.	100 ppm
Polyolefins max.	300 ppm
Cellulose (paper, wood)	100 ppm
Metals max.	100 ppm
Polyamide max.	100 ppm

Appendix B. Relationship between the key parameters for the evaluation scheme (EFSA CEF Panel, 2011)



**Default scenario (infant). For adults and toddlers, the migration criterion will be 0.75 and 0.15 µg/kg food, respectively.*

ABBREVIATIONS

bw body weight

CEF Food Contact Materials, Enzymes, Flavourings and Processing Aids

C*mod* modelled concentration in PET

C*res* residual concentrations in PET

EC European Commission

MPR Multi-Purpose Reactor

PET polyethylene terephthalate

PVC poly(vinyl chloride)